

IN THE UNITED STATES DISTRICT COURT FOR THE  
MIDDLE DISTRICT OF TENNESSEE  
NASHVILLE DIVISION

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RUTH SMITH, Individually and as Widow )  
for the Use and Benefit of Herself and the )  
Next of Kin of RICHARD SMITH, Deceased, ) Case #: 3:05-00444  
                                                  ) Judge Trauger  
                                                 Plaintiff, )  
                                                 )  
                                                 -against- )  
                                                 )  
PFIZER INC., PARKE-DAVIS, )  
a division of Warner-Lambert Company )  
and Warner-Lambert Company LLC, )  
WARNER-LAMBERT COMPANY, )  
WARNER-LAMBERT COMPANY LLC and )  
JOHN DOE(S) 1-10, )  
                                                 )  
                                                 Defendants. )  
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Qualifications of Plaintiff's Expert, Cheryl, Blume, Ph.D.

Dr. Cheryl Blume has dedicated her professional life to the development of pharmaceutical projects for submission to the United States Food and Drug Administration on behalf of pharmaceutical companies. She is currently the President of a company, Pharmaceutical Development Group, in Tampa, Florida. She works with and employs a team of people whose responsibilities are to assist drug companies in the evaluation of safety and efficacy information related to their drug products. These evaluations are made for the purpose of submitting to the FDA various Drug Applications so that drugs can be approved for sale in this country.

These evaluations and submissions of Drug Applications include the review of drug risks and benefits observed in patients taking the drug in question. Her work in this field also includes the composition, drafting, and submission of proposed labels for FDA approval and the composition, drafting, and submission of warnings, amendments, and corrections to existing labels for drugs already approved. Dr. Blume has performed this very type of work on more than 50 drugs.

Before her position with Pharmaceutical Development Group in Tampa, Florida, Dr. Blume was the Executive Vice President/Chief Operations Officer for Somerset Pharmaceuticals, Inc. (1993-1998), and she was a Vice President, Technical Director, and Director of Pharmacology at Mylan Laboratories, Inc., (1977-1995).

Dr. Blume was educated at West Virginia University where she received her Bachelor of Arts Degree in Biology, and she then went on to the West Virginia School of

Medicine where she obtained her Doctorate Degree in Medical Pharmacology and Toxicology.

Dr. Blume's experience with pharmacology has included research and development of neurotransmitter products during her time with Somerset and Mylan Pharmaceuticals, as well as with Drug Application submissions to the FDA during her work with Pharmaceutical Development Group. Dr. Blume has been awarded approximately 30 pharmaceutical patents, and about half deal with chemicals that impact neurotransmitters in the brain or are intended for use in diseases that may be impacted by neurotransmitters. Dr. Blume has authored or co-authored articles pertaining to issues such as pharmacology, pharmacokinetics, and the bioavailability of drugs.

Dr. Blume has also participated in educational forums. Her positions have included Affiliate Associate professor to the Voluntary Faculty of the Molecular Pharmacology & Physiology Department at the University of South Florida College of Medicine. At the University she has also been an Affiliate Research Scientist/Associated Professor to the Voluntary Faculty of the Department of Pharmacology.

Dr. Blume's participation in organizations within the pharmaceutical industry have included American Association of Pharmaceutical Scientists (AAPS); the American Pharmacists Associations; the Academy of Pharmaceutical Sciences; the Regulatory Affairs Professional Society (RAPS); the International Society of Pharmacoepidemiology (ISPE); the Drug Information Association (DIA); and the Generic Pharmaceutical Association (GPhA).